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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/244,984	02/04/1999	ROY A. BLACK	16761/153	4402

7590 06/20/2003

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WASHINGTON, DC 200075109

EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
1631	30

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/244,984

Applicant(s)

BLACK ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 41,42,56-63,66 and 75-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41,42,56-63,66 and 75-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/2/03 has been entered.

All rejections and objections not reiterated below are hereby withdrawn. Claims 41-42, 56-63, 66, and 75-81 are pending.

***Drawings***

The corrected or substitute drawings were received on 2/3/02. These drawings are accepted by the examiner.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-42 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

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to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

Applicant's arguments filed 4/2/03 have been fully considered but they are not persuasive. Applicant argues that the claim amendments render the rejection moot; however, as previously set forth, neither the prior art nor the specification teach how to identify an inhibitor, modulator or other regulator of TACE using only the method steps recited. The instant specification teaches on page 23 that the inventive methods may be used to identify potential inhibitory, mediatory, or regulatory compounds or compounds which have other binding effects, and discloses that one can evaluate the probability for synthesizing and testing inoperative compounds. It is well known in the art that not every compound which binds to an enzyme is an inhibitor. It is also well known a compound may bind to an enzyme without necessarily affecting its activity. For example, a compound which binds to a catalytic site may easily be an agonist instead of an antagonist. An antibody may bind to an epitope on an enzyme not involved in activity; or a compound may "associate" with the enzyme through very weak interactions and not affect activity at all. Water and/or salt molecules would be expected to associate with any polypeptide in solution, but do not necessarily inhibit, modulate, or regulate the activity of the polypeptide.

Claim 63 merely recites steps identifying a compound which "associates with" TACE; no steps of actually identifying an associating compound as an inhibitor, modulator, or regulator is recited in the claims. Claim 66 merely recites determining whether a compound "associates with" a catalytic domain. The instant specification teaches on pages 79-80 (Example 5) a method wherein a known inhibitor of TACE was modeled and "fitted" to a TACE catalytic site using atomic coordinates for both TACE and the inhibitor, then "specific candidate inhibitor-TACE interactions" were determined and used to identify other putative inhibitors. No step of determining or using specific candidate inhibitor-TACE interactions are recited in the rejected claims. Although the level of skill in the art is acknowledged to be high, in the absence of a step to identify whether the associating compound of claims 63 and 66 is indeed an inhibitor, modulator, or other regulator of TACE, it would require undue experimentation for one skilled in the art to determine whether the identified compound is an inhibitor, modulator, or other regulator of TACE. For these reasons, the examiner maintains that claims 41 and 42 are not enabled, and maintains the rejection.

***Claim Rejections - 35 USC § 101***

Claims 56-63, 66, and 75-81 are rejected under 35 USC 101 because the claimed invention lacks patentable utility.

Applicant's arguments filed 4/2/03 have been fully considered but they are not persuasive. Applicant argues that the examiner has required applicants to show utility for an unclaimed invention. In response, it is noted that, as admitted by applicant on

page 4 of the response, the claims are directed to methods of identifying compounds. The examiner agrees with applicant that utility of the method rests on whether the "results" of the method are concrete, tangible, and useful. As the "results" of the claimed methods are the compounds identified, the utility of the claimed methods rests on the utility of the compounds identified. As set forth in the MPEP 2107.01, a method of assaying for or identifying a material that itself has no specific and/or substantial utility does not have utility under 35 USC 101.

As previously set forth in the office action of 10/2/02, a method which identifies an inhibitor of TACE does provide a concrete, tangible and useful result, for the reasons set forth on page 2 of the instant specification. However, a method which only identifies a compound which interacts/associates with TACE does not provide a useful, concrete and tangible result, as the activity of the associating compound, and/or its effect on TACE, is completely unknown. Further research would have to be performed to determine what, if any, activity or effect the identified compound would have. It is noted that mere "association" with a catalytic domain or specific "pocket" is not evidence that a compound is necessarily an inhibitor of the enzyme. It is not known what effect a modulator or regulator other than an inhibitor would have on TACE, and thereby on  $\text{TNF}\alpha$  production (i.e. it is not known whether a compound which upregulates TACE necessarily result in higher levels of  $\text{TNF}\alpha$ ), therefore identification of a compound which merely modulates TACE production or activity is not a concrete, tangible, and useful result.

In response to applicant's argument that the BARONE declaration shows utility, it is noted that the BARONE declaration is directed toward enablement of a method using native TACE versus a modified TACE which comprises the coordinates of Table 1. As the BARONE declaration is not directed toward utility of the instant claims, this argument is moot.

For all of the reasons set forth above, the examiner maintains that the claims lack utility, and maintains the rejection.

### ***Conclusion***

No claims are allowed.

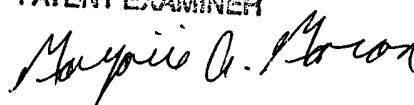
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN  
PATENT EXAMINER



mam  
June 12, 2003